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Johns-Manville

Internal Correspondence

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Subject: FDA PROPOSED SPECIFICATIONS ON TALC

Our memo to you dated August 29, 1973, was an emotion-charged exercize. It was intended to be just that in an effort to alert all involved as to the critical nature of the battle we now face.

This present memo on the same subject is a more calm assessment of the same situation. Given below are our analyses of some of the numbers presented by the FDA in their proposed specification and test method. Sid Speil suggested that we go through this particular exercize. It proves to be very productive. There are glaring inconsistencies that make the test method and specification completely incompatible.

On the one hand the FDA states that talc shall be 99.9 percent pure insofar as tremolite is concerned and 99.99 percent pure insofar as chrysotile is concerned. On the other hand, in their proposed test method, they permit a maximum of 1,000 tremolite fibers and 100 chrysotile fibers. Only fibers 5 microns or greater in length with an aspect ratio of 3/1 or greater are counted. Here is where the complete ambiguity and inconsistency is involved.

If we assume that FDA is going to base their requirement on percent purity and that they really mean 99.99 percent pure insofar as chrysotile is concerned, then up to 0.01 percent chrysotile would be permitted. In terms of fiber count then the number of fibers permitted would depend on the size of the fiber. The smaller the fiber, the less they weigh and more would be permitted. For example, 38,500 fibers 0.5 x 5.0 microns would amount to 0.01 percent by weight. If we assume a larger fiber size at 1.5 x 50.0 microns then 435 fibers by microscopic count would amount to 0.01 percent. These numbers are far from the 100 maximum mentioned in the test method.

For tremolite the numbers are even more startling. The specification calls for the talc to be 99.9 percent free of tremolite. In other words, up to 0.1 percent tremolite would be permitted. This would mean that on a weight percent basis

the talc could contain up to 345,000 tremolite particles 0.5 x 5.0 microns in size or 3,850 tremolite particles 1.5 x 50.0 microns in size. Again, these numbers are quite different from the 1,000 maximum described in the FDA test method.

Looking at these inconsistencies the opposite way--in terms of indicated percent purity as defined by number counts of 1,000 and 100 for tremolite and chrysotile respectively--the data are mind-boggling!

For example, 1,000 fibers of tremolite 0.5 x 5.0 microns in size works out to only 0.0003 percent by weight. The talc would have to be 99.9997 percent pure! Another example: 1,000 fibers of tremolite 1.5 x 50.0 microns in size amounts to 0.03 percent by weight. In this case the talc would have to be 99.97 percent pure. These are quite different from the 99.9 percent purity mentioned in the proposed specification.

Looking at chrysotile the same way, 100 fibers 0.5 x 5.0 microns amounts to 0.00003 percent by weight. With fibers 1.5 x 50.0 microns in size the weight is 0.002 percent. In other words purities of 99.99997 percent and 99.998 percent would be required! These numbers are <u>really</u> mind-boggling! It is almost impossible to obtain <u>reagent grade analytical chemicals</u> of this state of purity. Here are a few examples:

Baker Analyzed Reagent Grade Sodium Chloride is only 99.9 percent NaCl.

Baker Analyzed Reagent Grade Sodium Carbonate is only 99.7 percent Na_2CO_3.

Baker Analyzed Reagent Grade Calcium Chloride is only 98.4 percent $CaCl_2$.

Baker Analyzed Reagent Grade Potassium Nitrite is only 98.8 percent KNO_2.

Baker Analyzed Reagent Grade Potassium Hydroxide is only 85.2 percent KOH.

The FDA is calling for talc purities out to the <u>fifth</u> decimal point! Truly mind-boggling!!

R. S. Lamar

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